



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Washington, DC 20204

JUN 13 2000

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Richard F. Staack, Ph.D.
Senior Scientist
Cognis Nutrition and Health
5325 South Ninth Avenue
La Grange, Illinois 60525-3602

Dear Dr. Staack:

This is in response to your letter to the Food and Drug Administration (FDA), dated June 1, 2000, pursuant to 21 U.S.C. 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the Act)). Your submission states that Cognis Nutrition and Health is making the following claim, among others, for the dietary ingredient Prevastein™, which is composed of soy isoflavones:

“In animal models that mimic women’s postmenopausal years, studies by Arjmandi and colleagues have demonstrated that a diet containing isoflavones within soy helped maintain bone density.”

21 U.S.C. 343(r)(6) makes clear that a statement included in labeling under the authority of that section may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases. The statement that you are making for products containing soy isoflavones suggests that they are intended to treat, prevent, or mitigate a disease, namely osteoporosis. This claim does not meet the requirements of 21 U.S.C. 343(r)(6). This claim suggests that these products are intended for use as drugs within the meaning of 21 U.S.C. 321(g)(1)(B), and that they are subject to regulation under the drug provisions of the Act. If you intend to make claims of this nature, you should contact FDA’s Center for Drug Evaluation and Research (CDER), Office of Compliance, HFD-310, 7520 Standish Place, Rockville, Maryland 20855.

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Please contact us if we may be of further assistance.

Sincerely,

John B. Foret
Director
Division of Compliance and Enforcement
Office of Nutritional Products, Labeling,
and Dietary Supplements
Center for Food Safety
and Applied Nutrition

Copies:

FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-300
FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of
Enforcement, HFC-200
FDA, Chicago District Office, Compliance Branch, HFR-MW140

cc:

HFA-224 (w/incoming)
HFA-305 (docket 97S-0163)
HFS-22 (CCO)
HFS-800 (file, r/f)
HFS-811 (r/f, file)
HFD-40 (Behrman)
HFD-310
HFD-314 (Aronson)
HFS-605
HFV-228 (Betz)
GCF-1 (Nickerson, Dorsey)
f/t:rjm:HFS-811:6/13/00:cognis.adv:disc48



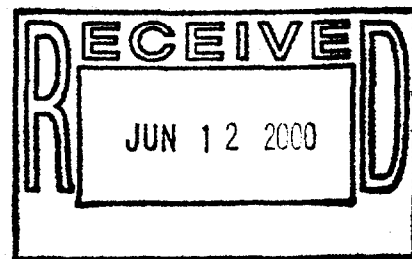
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1, June, 2000

nutrition&health

Office of Special Nutritionals (HFS-450)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 C Street SW
Washington, DC 20204



To the Food and Drug Administration:

Pursuant to section 403(r)(6) for the Federal Food, Drug, and Cosmetic Act (FDC Act), 21.U.S.C. § 343 (r)(6), we hereby notify the FDA that Cognis Corporation has included the following statements in labeling for a dietary ingredient that it manufactures and markets for use in dietary supplement products.

The following information is provided:

1. The name and address of the manufacturer and distributor of the dietary ingredient is as follows: Cognis Corporation, 5325 South 9th Avenue, LaGrange, IL 60525-3602.

2. The text of the labeling statements is as follows:

"... researchers also suggest that isoflavones may compete for estrogen receptors with estrogen, exerting an antiestrogenic effect."

"Isoflavones function as important regulators of cell growth and behavior. For example, they inhibit the activity of tyrosine kinase, an enzyme that may be involved in some harmful processes."

"As antioxidants, genistein and daidzein protect the body's cells from the damaging effects of molecules called free radicals."

"The multifaceted properties of soy isoflavones (antioxidant, mild estrogen, and cell regulator activities) act naturally to moderate a woman's own hormone levels."

"...diets high in natural estrogens may help maintain normal heart function, hormonal balance, and bone health."

"Population-based studies have found that Asian men, who eat traditional high-soy diets, are more likely to maintain normal prostate health than men in the United States and other Western nations."

"Epidemiological, animal and clinical evidence suggests that increased dietary intake of soy containing isoflavones is associated with the promotion of cardiovascular health."

"In Asia, evidence supports the hypothesis that consumption of soy derived isoflavones helps promote cardiovascular health."

"...diets rich in isoflavones help maintain normal serum lipoprotein levels."

"...research suggests that dietary isoflavones consumed may account for these differences in that they may act as weak, natural estrogens in women with low estrogen levels."

"Clinical studies to date suggest isoflavones act as weak estrogens helping women who seek a natural solution to alleviate common symptoms associated with reduced or altered levels of endogenous estrogen."

"Isoflavones are referred to as phytoestrogens because of the estrogen-like activity they impart suggesting to scientists that naturally occurring isoflavones from soy may have beneficial effects on bone."

"In animal models that mimic women's postmenopausal years, studies by Arjmandi and colleagues have demonstrated that a diet containing isoflavones within soy helped maintain bone density."

"...both clinical and animal studies suggest that isoflavones present in soy protein are one approach to help preserve bone density."

3. The dietary ingredient that is the subject of the statements is soy isoflavones. The brand name for this ingredient is PREVASTEIN™.

4. We do not manufacture or distribute retail dietary supplement products but only bulk dietary ingredients used by others in their manufacture of their dietary supplements. The information provided above relates to the

labeling that will be used by Cognis Corporation and for which Cognis Corporation is responsible.

Pursuant to FDA regulations concerning "notification procedures for certain types of statements on dietary supplements," 21C.F.R. § 101.93, I certify that, to the best of my knowledge and in my opinion, the information contained in this notice is complete and accurate, and that Cognis Corporation has substantiation that the statements are truthful and not misleading.

We trust this provides the information that is needed. If you should have any questions, please just let us know.

Sincerely,

A handwritten signature in black ink that reads "Richard F. Staack". The signature is written in a cursive, flowing style.

Richard F. Staack, Ph.D.
Senior Scientist
Cognis Nutrition and Health